K953979

Confidential *Attachment 7*

JUL 25 1996

ATTACHMENT 7

510 (k) SUMMARY

This Attachment contains the HealthTech Services Corporation summary of the HANC™ Network 510(k) Submission

510(k) SUMMARY
THE HANC™ NETWORK

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: June 24, 1995

Name of Device and Name/Address of Sponsor

The HANC™ Network
HealthTech Services Corporation
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Common or Usual Name: Home Assisted Nursing Care (HANC™)

Classification Name: FDA has not specifically classified the device, however based on communications with the Agency, HealthTech Services Corporation was advised to make the HANC™ Network an accessory to a Semi-Automatic Indirect Blood Pressure Monitor. Semi-Automatic Indirect Blood Pressure Monitors along with their accessories, are classified under 21 C.F.R. § 870.1130 as Class II devices. The product code for such devices is 74DXN.

Predicate Devices:

Overall Predicate

The Buddy System
510(k) #: **K864318**

Vital Sign Component Predicates

Blood Pressure	Nellcor Symphony™ N-3100 BP Monitor	**K945947**
ECG	BCI 9100 Multigas Monitor	**K921388/B**
ECG electrodes	NDM Tracets 3000	**K875015**
Temperature	BCI 9100 Multigas Monitor	**K921388/B**
Temperature Probe	Criticon Dinamap™ 8100T Vital Signs Monitor	**K874378**
Pulse Oximetry	BCI 9100 Multigas Monitor	**K921388/B**
Electronic Stethoscope	Andries Tek Electronic Stethoscope	**Pre-1976 Device**

Intended Use

The HANC™ Network is intended to be used as a clinical tool to provide a method of monitoring a patient's health status at home and a method for transferring the data to a nurse for review. The HANC™ Network is indicated for use for patients that require medical observation and monitoring while at home, who have medication or therapy compliance issues, and who need training reinforcement. The HANC™ Network is not a patient emergency response system. It does not analyze patient information and does not offer medical advice to the patient. It collects, stores, and transmits patient information to the health professional.

Technological Characteristics and Substantial Equivalence

The HANC™ Network is a patient-support system designed to enhance the quality and lower the cost of healthcare services. The system consists of two parts: (1) a programmable device called the Home Assisted Nursing Care ("HANC™") unit that monitors and transmits health information from a remote site such as a patient's home; and (2) a Remote Nursing Interface that receives, stores, and prints data for nurse or physician review.

The HANC™ unit is a speech and/or touch screen-activated device designed to monitor and assist patients in their homes. It coaches the patient in a conversational manner and manages patient schedules, takes vital signs, and has the ability to communicate over phone lines with an off-site Remote Nursing Interface that provides monitoring of the patient. The HANC™ unit may be used to perform

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measurements of pulse, blood pressure, temperature, blood oxygen saturation, and electrocardiogram (ECG). In addition, the HANC™ unit incorporates other features such as recording stethoscope sounds, capturing a video image, reminding patients to take medications, coaching screens, inputing data manually, and calling the nurse.

The HANC™ Network is substantially equivalent to the Buddy System, referenced above. The HANC™ Network and its predicate both have the same general intended use, similar principles of operation, and similar technological characteristic. Both are intended to assist patients in managing their health at home and to provide a method for the clinician to gather medical data remotely. Both home devices utilize previously cleared Original Equipment Manufacturer (OEM) components to measure blood pressure, ECG, temperature and both products contain additional features such as medication reminders, coaching screens, and symptom reporting.

Likewise, in addition to the HANC™ Network's overall substantial equivalence to the Buddy System, each vital sign component of the HANC™ unit also is substantially equivalent to the pertinent cleared device in stand-alone form. The individual vital sign components of the HANC™ unit are OEM components that are each currently used in other previously cleared medical devices. Thus, each of the vital sign components integrated into the HANC™ unit is substantially equivalent to its stand-alone FDA-cleared counterpart.

The differences between the HANC™ Network and its predicate device are very minor. For example, the HANC™ Network incorporates additional features such as an electronic stethoscope, a pulse oximeter, and a camera, as well as newer and more advanced electronics. Therefore, HealthTech Services believes that the minor differences between the HANC™ Network and its predicate device do not substantially change either the performance of the HANC™ unit as compared to the Buddy unit, or the safety, efficacy, or intended use of the HANC™ Network as compared to the Buddy System.

Performance Data

HealthTech Services has performed vital sign testing, and electrical, mechanical and environmental testing. The vital sign testing was designed to validate the design of the HANC™ unit and to demonstrate that the HANC™ unit is able to accurately and reliably measure vital sign parameters. It also was designed to ensure that integration of the previously cleared stand-alone components into the HANC™ unit will not affect the performance or operation of those components. The electrical, mechanical, and environmental testing performed was designed to demonstrate the safety and effectiveness of the performance characteristics of the product.

In all instances the HANC™ unit performed as expected and passed the test performed. The vital sign tests have shown that integration of the vital sign components into the HANC™ unit does not in any way affect their performance characteristics. In addition, the electrical, mechanical and environmental testing has shown that the HANC™ unit is both safe and effective in the home environment.

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